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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,634	07/10/2001	Avi Ashkenazi	10466/67	1375

30313 7590 08/29/2005

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,634	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claim 39 has been amended as requested in the amendment filed on July 05, 2005. Following the amendment, claims 39-43 are pending in the instant application.

Claims 39-43 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on July 05, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claims 39-43 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in previous communication from the office.

At pages 3-5 of the Response, Applicant discusses issues related to legal standards of utility rejections and refers to the Utility Examination Guidelines. Applicant argues that "a utility

is "specific" when it is particular to the subject matter claimed" and refers to *Nelson v. Bowler* to support a statement regarding "specific" therapeutic use". Applicant also cites *Cross v. Iizuka* and submits that *in vitro* results are sufficient to support practical asserted *in vivo* utility. Applicant further discusses what constitutes "a substantial utility" with respect to the interpretation of the phrase "immediate benefit to the public" (see page 6 of the Response). Applicant's arguments have been carefully considered but are not persuasive for the reasons that follow.

Applicant asserts the utility of the claimed antibodies to a polypeptide comprising SEQ ID NO: 91 (PRO266 polypeptides) as "useful to prevent tumor invasiveness, and/or possibly, to destroy tumor cells" (page 7 of the Response) based on the positive experimental data obtained in the skin vascular permeability assay as disclosed in Example 77. As fully explained in the previous office actions of record, based on the information presented in the instant specification, as filed, one skilled in the art would reasonably conclude that the disclosed PRO266 polypeptides could represent a novel proinflammatory molecule. However, since the instant specification fails to provide any evidence or sound scientific reasoning that would allow a conclusion that antibodies to this instant alleged proinflammatory polypeptide of SEQ ID NO: 91 are useful in treating any particular form of cancer, or are capable of destroying tumor cells, or to treat any or all of autoimmune diseases, Applicant's asserted utility for the antibodies to the polypeptide of SEQ ID NO: 91 constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use (see *Brenner v. Manson*). This type of utility is not considered a "substantial utility". While disclosure of a polypeptide that has a stated correlation to a specific disease condition would be considered a "specific and substantial" utility

in the context of identifying potential candidates for clinical or preventive measures, in the instant case the polypeptide is suitable only for additional research. Therefore, if the polypeptide of SEQ ID NO: 91 does not a substantial or well-established utility as a therapeutic target, then the specific and substantial utility of an antibody that binds to the polypeptide of SEQ ID NO: 91 is clearly lacking.

Applicant's arguments that "[t]he discovery of PRO266 as a proinflammatory molecule provides for the first time the ability to exploit this target as a therapeutic agent for treating [invasive cancers or autoimmune diseases]" (bottom at page 9 of the Response) are not persuasive particularly in view of the absence of information of the biological activity of PRO266 polypeptides or the type of cancer or autoimmune disease to be treated. The art clearly recognizes that class of proinflammatory molecules is characterized by broad range of activities (see reasons of record in the previous office action, for example). Therefore, in order to use antibodies to PRO266 polypeptides "against autoimmune diseases", for example (bottom at page 9 of the Response), a skilled practitioner would have to first perform a substantial amount of further research to establish its practical utility by discovering the biological role of PRO266 with respect to a particular disease or condition.

Thus, for the reasons set forth and also reasons of record in previous communications from the office, the claimed antibodies do not have a real-world use and do not meet the utility requirement under 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. Claims 39-43 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

August 22, 2005